UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/335,581	06/18/99	BANNAN J	2016-4010US2

HM12/0912

MORGAN AND FINNEGAN LLP
345 PARK AVENUE
NEW YORK NY 10154

EXAMINER	
MINNIFIELD,N	
ART UNIT	**PAPER NUMBER**
1645	3

DATE MAILED: 09/12/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/335,581	BANNAN ET AL
Examiner	**Group Art Unit**
N. M. Minnifield	1645

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-49 is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-49 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

CRF Notice attached

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Full compliance with the sequence rules is required in response to this office action. A complete response to this office action should include both compliance with the sequence rules and a response to the election/restriction requirement set forth below. Failure to fully comply with ***both*** these requirements in the time period set forth in this office action will be held non-responsive.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, drawn to a peptide, classified in class 530, subclass 350.

II. Claims 7 and 8, drawn to a pharmaceutical composition, classified in class 424, subclass 237.1.

III. Claims 9-13 and 24, drawn to a method of inducing serum antibodies that bind at least one enterotoxin or exotoxin, administering a peptide, classified in class 424, subclass 184.1.

IV. Claims 14-16 and 24, drawn to a method of inducing serum antibodies which detect toxins, administering peptide, classified in class 424, subclass 184.1.

V. Claims 17-19 and 24, drawn to a method of inducing serum antibodies which inhibit blastogenesis of human mononuclear cells, administering an antibody classified in class 424, subclass 184.1, 165.1+.

VI. Claims 20-24, drawn to a method of passive immunization, classified in class 530, subclass 387.1, 388.1; class 424, subclass 130.1+.

VII. Claims 25-29, drawn to nucleic acids, classified in class 536, subclass 23.1.

VIII. Claims 30 and 31, drawn to methods of inducing serum antibodies that binds enterotoxin or exotoxin, administering nucleic acids, classified in class 514, subclass 45.

IX. Claim 32, drawn to antibodies, classified in class 530, subclass 388.1, 387.1.

X. Claim 33, drawn to methods for detecting the presence of a toxin using an antibody, classified in class 435, subclass 7.2, 7.33, 7.34.

XI. Claims 34 and 35, drawn to methods for detecting the presence of antibodies to staphylococcus or streptococcal toxins using a peptide, classified in class 436, subclass 518, 7.2, 7.33, 7.34.

XII. Claims 36-38, drawn to kits, classified in class 435, subclass 975.

XIII. Claims 39-44 and 49, drawn to a method of inhibiting blastogenesis of human mononuclear cells, administering peptides, classified in class 424, subclass 184.1.

XIV. Claims 45-49, drawn to a method of protecting a mammal, administering a peptide, classified in class 424, subclass 234.1, 237.1; class 514, subclass 12.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, VII, IX, and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MEP. § 806.04, MEP. § 808.01). In the instant case the different inventions the different inventions are products that have different functions and they materially, biochemically, structurally and functionally different.

Inventions III, IV, V, VI, VIII, X, XI, XIII, and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different

functions, or they have different effects. (M.E.P.. § 806.04, M.E.P.. § 808.01). In the instant case the different inventions are methods; these different methods have an effect on different systems and the final effect is different for each method, different modes of operation, different steps and components/reagents are used.

Inventions I/II/VII/IX/XII and III/IV/V/VI/VIII/X/XI/XIII/XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.E.P.. § 806.05(h)). In the instant case the products (peptides and compositions) can be used to make antibodies for immunopurification or in immunoassays or recombinant methods to produce more peptides. The antibodies can be used for affinity chromatography. Other products can be used in the methods claims to achieve the same or similar result, inducing serum antibodies to inhibit or bind. The nucleic acid products can be used as probes and primers.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for one Group is not required for another Group , restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. This application contains claims directed to the following patentably distinct species of the claimed invention: SEQ ID No 28, 29 and those SEQ ID No 3-8 as set forth in the markush group of claim 4. Further, should Applicants elect SEQ ID NO:28 or 29, Applicants should elect an single specific sequence of all those possibilities set forth in SEQ ID NO:28 or 29; see claims 1 and 2 for the numerous possibilities.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, SEQ ID No. 28 (CMYGGVTLHEGN) as set forth in claim 3 is considered generic.

The claims are generic to a plurality of disclosed patentably distinct species comprising numerous possibilities of the peptide. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.E.P.. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions

unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is (703) 305-3394. The examiner can normally be reached on Monday-Thursday from 7:00 AM-4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R. F. Smith, can be reached on (703) 308-3909. The fax phone number for Technology Center 1600 is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

N. M. Minnifield

August 30, 2000

NITA MINNIFIELD
PRIMARY EXAMINER 8/30/00

Application No.: 08/335581

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: Applicant should follow the format of the attached sample statement to request that the CRF filed in the parent application be used to create a CRF in this application.

Applicant Must Provide:

☒ An Initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☐ An Initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
For PatentIn software help, call (703) 308-6856

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE

Sample Statement

Sample Request to Use Computer Readable Form from Another Application

The following paragraph, or language having the same effect, can be used to invoke the procedures of 37 CFR section 1.821(e) in which an identical computer readable form from another application is used in a given application. The paragraph should be incorporated into a separate paper to be submitted in the given application:

> The computer readable form in this application, 08/100,000, is identical with that filed in Application Number 07/999,999, filed March 1, 1988. In accordance with 37 CFR 1.821(e), please use the [first-filed, last-filed or only, whichever is applicable] computer readable form filed in that application as the computer readable form for the instant application. It is understood that the Patent and Trademark Office will make the necessary change in application number and filing date for the computer readable form that will be used for the instant application. A paper copy of the Sequence Listing is [included in the originally-filed specification of the instant application, included in a separately filed preliminary amendment for incorporation into the specification, whichever is applicable].